

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

**SHIRE DEVELOPMENT LLC,
SHIRE CANADA INC., and
SHIRE INTERNATIONAL LICENSING B.V.,**

Plaintiffs,

v.

**APOTEX, INC. and
APOTEX CORP.,**

Defendant.

C. A. No. 15-1045-LPS-CJB

[PROPOSED] PROTECTIVE ORDER

WHEREAS Plaintiffs Shire Development LLC, Shire Canada Inc., and Shire International Licensing B.V. (collectively, “Plaintiffs”) and Defendants Apotex, Inc. and Apotex Corp. (collectively “Defendants”) are currently litigating the above-referenced patent-infringement action (the “Action”), which is likely to involve discovery of documents and testimony containing trade secrets and other confidential research, development, regulatory, and commercial information of the parties to this Action and third parties, including confidential and commercially sensitive information relating to business strategies, manufacturing and distribution capabilities, sales, costs, pricing, profitability, customers, suppliers, and other business and financial data; and

WHEREAS this confidential information may be disclosed in providing initial disclosures, responding to written discovery requests, producing documents, providing testimony by way of deposition, conducting motion practice before the Court or otherwise in these

proceedings, and must be protected in order to preserve the legitimate business interests of the parties; and

WHEREAS good cause exists for entry of this Protective Order, *see* Fed. R. Civ. P. 26(c), *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994); and

WHEREAS the parties in their business practices have gone to great lengths to safeguard and protect the confidentiality of the documents and information, and the disclosure of which would pose a substantial risk of irreparable harm to the producing party's legitimate proprietary interests; and

WHEREAS this Protective Order provides reasonable restrictions on the disclosure of such sensitive materials of a confidential nature; and

WHEREAS all parties agree to the terms of this Protective Order to protect their confidential documents and information; and

THEREFORE, in view of the foregoing and because the parties hereto, by and through their respective counsel, have stipulated to the entry of the following Protective Order pursuant to Federal Rule of Civil Procedure 26(c), and the Court having determined that good cause exists for the entry of this Protective Order,

IT IS HEREBY STIPULATED AND ORDERED THAT the following procedures shall be employed and the following restrictions shall govern the handling of documents, depositions, pleadings, exhibits, and all other information exchanged by the parties in this Action, or provided by or obtained from non-parties in this Action:

1. Any party to this Action and any third party shall have the right, subject to this Protective Order, to designate as "Confidential" any information, document, or thing, or portion of any document or thing that: (a) contains private or confidential personal information, (b)

contains information received in confidence from third parties, or (c) the producing party otherwise believes in good faith to be entitled to protection under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure. Any party to this Action or any third party who, subject to this Protective Order, produces or discloses any material designated as Confidential, including without limitation any information, document, thing, interrogatory answer, admission, contention, pleading, or testimony, shall mark the same with the foregoing or similar legend: “CONFIDENTIAL” or “CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER” (hereinafter “Confidential”).

2. Any party to this Action and any third party shall have the right, subject to this Protective Order, to designate as “Highly Confidential” any information, document, or thing, or portion of any document or thing that contains (a) trade secrets, (b) competitively sensitive technical, marketing, financial, sales, or other confidential business information, or (c) highly sensitive personal information, the disclosure of which is highly likely to cause significant harm to an individual or to the business or competitive position of the designating party. Such information includes the producing party’s: (1) competitive business or highly sensitive commercial information (including, for example, business plans, business strategies, negotiations, and license agreements); (2) financial information (including, for example, budgeting, accounting, sales figures, and sales forecasts); (3) business-relationship information (including, for example, information pertaining to potential and/or existing customers, competitors, suppliers, distributors, affiliates, subsidiaries, and parents); (4) personnel information (including, for example, compensation, evaluations, and other employment information); (5) research-and-development information regarding products currently in development or undergoing FDA approval (including, for example, laboratory notebooks,

development reports, testing records, and research plans; and (6) regulatory information and non-public information concerning drug applications and commercial products, and non-public communications with the United States Food and Drug Administration (“FDA”) or other regulatory agencies regarding products currently in development or undergoing FDA approval. Any party to this Action or any third party who produces or discloses material designated as Highly Confidential, subject to this Protective Order, including without limitation any information, document, thing, interrogatory answer, admission, pleading, or testimony, shall mark the same with the foregoing or similar legend: “HIGHLY CONFIDENTIAL” or “HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL ONLY” (hereinafter “Highly Confidential”).

All Confidential and Highly Confidential material shall be used by the receiving party solely for purposes of the prosecution or defense of this Action, shall not be used by the receiving party for any business, commercial, competitive, personal, or other purpose, and shall not be disclosed by the receiving party to anyone other than those set forth in Paragraph 4 (for Confidential information) and Paragraph 5 (for Highly Confidential information), unless and until the restrictions herein are removed either by written agreement of counsel for the parties, or by Order of the Court. Confidential or Highly Confidential material shall not be disclosed to any person who is involved in patent prosecution relating to the patents-in-suit or any other patents or patent applications directed to lanthanum carbonate or formulations containing lanthanum carbonate. *See In re Deutsche Bank*, 605 F.3d 1373 (Fed. Cir. 2010). However, prohibited “patent prosecution” shall not include reissue proceedings that do not broaden the scope of the claims, reexamination proceedings, *inter partes* reviews, post-grant reviews, or other contested proceedings in which the scope of existing claims is not broadened.

3. It is understood that counsel for a party may give advice and opinions to his or her client relating to the above-captioned Action based on his or her evaluation of Confidential or Highly Confidential material, provided that such advice and opinions shall not reveal the content of the Confidential or Highly Confidential material except by prior written agreement of counsel for the parties, or by Order of the Court. Nothing herein shall prohibit communications with the U.S. Food and Drug Administration (“FDA”) or the United States Patent and Trademark Office concerning the status of this Action or responding to the FDA regarding the party’s own NDA or ANDA or communications regarding obtaining or maintaining approval under the party’s own NDA or ANDA, including advising the client or responding to inquiries concerning carve-outs, exclusivities, launch dates, and/or responding to citizen petitions. However, no Confidential or Highly Confidential material of the other party shall be used as a basis for preparing a Citizen’s Petition or in connection with any other activities at FDA or in subsequent litigation involving FDA.

4. Confidential material and the contents of Confidential material may be disclosed only to the following individuals under the following conditions:

- a. Outside counsel (herein defined as a party’s outside counsel of record, including necessary paralegal, secretarial, and clerical personnel assisting such counsel, including, but not limited to, photocopying and graphics services);
- b. Jury consultants, mock judges/jurors, and third-party graphics/trial support vendors retained by outside counsel who have signed the undertaking attached as Exhibit A to this Protective Order;

- c. Subject to the provisions of Paragraph 6 of this Protective Order, one in-house counsel for a party who has signed the undertaking attached as Exhibit A to this Protective Order;
- d. A stenographer and videographer recording testimony concerning the information;
- e. Subject to the provisions of Paragraph 7 of this Protective Order, experts and consultants and their staff whom a party employs for purposes of this Action only; and
- f. The Court and personnel assisting the Court.

5. Highly Confidential material and the contents of Highly Confidential material may only be disclosed to any person identified in Paragraphs 4(a), (b), (d), (e), and (f).

6. A party may not disclose Confidential material to an in-house counsel pursuant to Paragraph 4(c) of this Protective Order until after the in-house counsel has signed an undertaking in the form of Exhibit A to this Protective Order. At least five (5) business days before the first disclosure of Confidential material to an in-house counsel, the party obtaining the undertaking must serve it via e-mail on all other parties. If the producing party has good cause to object to the disclosure, it must serve the party proposing to make the disclosure with a written objection within five (5) business days after service of the identification. Unless the parties resolve the dispute within five (5) business days after service of the objection, or a longer period if the parties so agree, the producing party must move the Court promptly for a ruling, and the Confidential information may not be disclosed to the in-house counsel without the Court's approval.

7. A party may not disclose Confidential or Highly Confidential material to an expert or consultant pursuant to Paragraph 4(e) or Paragraph 5 of this Protective Order until after the expert or consultant has signed an undertaking in the form of Exhibit A to this Protective Order. At least five (5) business days before the first disclosure of Confidential or Highly Confidential material to an expert or consultant (or member of their staff), the party proposing to make the disclosure must serve by email on all other parties a written identification of the expert or consultant and: (i) the expert's or consultant's signed undertaking in the form of Exhibit A to this Protective Order; (ii) a copy of his or her curriculum vitae; and (iii) a list of all other cases in which, during the previous four (4) years, the expert or consultant testified at trial or by deposition. If the producing party has good cause to object to the disclosure (which does not include challenging the qualifications of the expert or consultant), it must serve the party proposing to make the disclosure with a written objection within five (5) business days after service of the identification. Unless the parties resolve the dispute within five (5) business days after service of the objection, or a longer period if the parties so agree, the producing party must move the Court promptly for a ruling, and the Confidential or Highly Confidential material may not be disclosed to the expert or consultant without the Court's approval.

8. Notwithstanding Paragraph 4 and Paragraph 5, a party may disclose Confidential or Highly Confidential material at a deposition, a hearing, or at trial to: (i) any employee of the producing party; (ii) any person, no longer affiliated with the producing party, who authored or received the information in whole or in part; (iii) any person who, based on evidence, is reasonably believed to have had access to or knowledge to the information before this Action was filed; (iv) a producing party's designee under Federal Rule of Civil Procedure 30(b)(6); and

(v) any person to whom the producing party consents to such disclosure in writing or orally on the record.

9. A party who wishes to disclose Confidential or Highly Confidential material to a person not authorized under Paragraph 4 or Paragraph 5 of this Protective Order to receive such material must first make a reasonable attempt to obtain the producing party's permission by serving a written request upon counsel for the producing party before the date of the proposed disclosure. Such request shall specifically identify the Confidential or Highly Confidential material, including production number, sought to be so disclosed and the name, title and function of the person(s) to whom such disclosure is desired to be made. The producing party shall thereafter respond to the request in writing within seven (7) business days after receipt of same. Absent good cause shown, a failure to respond within such time shall constitute consent to the request. If, where consent has been withheld, the parties are subsequently unable to agree on the terms and conditions of the requested disclosure, the matter may be submitted to the Court for resolution by the party seeking disclosure. Such disclosure shall be postponed until a ruling has been obtained from the Court.

10. A person designates information in deposition testimony as Confidential or Highly Confidential by stating on the record at the deposition that the information is Confidential or Highly Confidential or by advising the opposing party and the stenographer and videographer in writing that the information is Confidential or Highly Confidential. Whether or not designation is made at the time of a deposition, all depositions shall be treated as Highly Confidential from the taking of the deposition until thirty (30) days after receipt of the final transcript. At any deposition, to the extent Confidential or Highly Confidential documents are used or Confidential or Highly Confidential information is discussed, at the request of either

party, the room will be closed to anyone other than the individuals designated to have access to such information pursuant to Paragraphs 4 and 5 of this Protective Order unless otherwise agreed upon by the parties on a deposition-by-deposition basis.

11. If counsel for a party receiving documents or information designated as Confidential or Highly Confidential hereunder objects to such designation of any or all of such items (or portions thereof), the following procedure shall apply:

- a. Counsel for the objecting party shall serve on the designating party or third party a written objection to such designation, which shall describe with particularity the documents or information (or portions thereof) in question and shall state the grounds for objection. Counsel for the designating party or third party shall respond in writing to such objection within seven (7) business days, and shall state with particularity the grounds for asserting that the document or information (or portions thereof) is Confidential or Highly Confidential. If the designating party or third party makes a timely response to such objection asserting the propriety of the designation, counsel shall then confer in good faith in an effort to resolve the dispute.
- b. If a dispute as to a Confidential or Highly Confidential designation of a document or item of information cannot be resolved by agreement, the proponent of the designation being challenged shall present the dispute to the Court. The document or information that is the subject of the filing shall be treated as originally designated pending resolution of the dispute.

12. Any party filing with the Court any Confidential or Highly Confidential material shall make such filing under seal in accordance with Local Civil Rule 5.1.3, the United States District Court for the District of Delaware's CM/ECF procedures, and any other procedures required by the Court. The burden of proving to the Court that such material should be sealed shall at all times remain with the party that initially disclosed and designated the subject material as Confidential or Highly Confidential under the terms of this Protective Order. If the filing party is not the designating party and is unaware of the specific basis for the designating party's having designated the subject material as Confidential or Highly Confidential, then the filing party nonetheless is obligated to make a reasonable effort when filing the subject material to seal such material. In the event the filing party takes exception to any designation of the subject material by the designating party, then the filing party shall seek relief from such designation pursuant to the procedures set forth in this Protective Order.

13. To the extent consistent with applicable law, the inadvertent or unintentional disclosure of Confidential or Highly Confidential material that should have been designated as such, regardless of whether the information, document, or thing was so designated at the time of disclosure, shall not be deemed a waiver in whole or in part of a party's claim of confidentiality, either as to the specific information, document, or thing disclosed or as to any other material or information concerning the same or related subject matter. Such inadvertent or unintentional disclosure may be rectified by notifying in writing, within a reasonable time after the discovery of such inadvertent disclosures, counsel for all parties to whom the material was disclosed that the material should have been designated Confidential or Highly Confidential. Such notice shall constitute a designation of the information, document, or thing as Confidential or Highly Confidential under this Protective Order.

14. When the inadvertent or mistaken disclosure of any information, document, or thing protected by privilege, work-product immunity, or any other applicable protection is discovered by the producing party and brought to the attention of the receiving party, the receiving party's treatment of such material shall be in accordance with Federal Rule of Civil Procedure 26(b)(5)(B). Such inadvertent or mistaken disclosure of such information, document, or thing shall not by itself constitute a waiver by the producing party of any claims of privilege, work-product immunity, or any other applicable protection. The producing party's notification to the receiving party shall constitute reasonable precautions to prevent disclosure and reasonably prompt measures to rectify the inadvertent production within the meaning of Federal Rule of Evidence 502(b)(3). The producing party must disclose the basis for its assertion of privilege by listing any inadvertently produced documents on a privilege log within five (5) business days following notification of the inadvertent production to the receiving party. For purposes of this Paragraph, it shall be irrelevant which party initially discovers the inadvertently or mistakenly produced information, documents, or tangible items that are otherwise properly subject to a claim of attorney-client privilege, work-product immunity, or any other applicable protection. However, nothing herein restricts the right of the receiving party to challenge the producing party's claim of protection if appropriate within a reasonable time after receiving notice of the inadvertent or mistaken disclosure.

15. No information that is in the public domain or which is already known by the receiving party through proper means, or which is or becomes available to a party from a source other than the party asserting confidentiality, where such source is rightfully in possession of such information on a non-confidential basis, shall be deemed or considered to be Confidential or Highly Confidential material under this Protective Order.

16. Upon receipt of any request or subpoena for Confidential or Highly Confidential material, the party receiving the request or subpoena shall immediately notify outside counsel of record for the producing party of the request or subpoena, so that the latter may protect its interests.

17. This Protective Order shall not deprive any party of its right to object to discovery by any other party or on any otherwise permitted ground. This Protective Order is being entered without prejudice to the right of any party to move the Court for modification of or for relief from any of its terms.

18. Within sixty (60) calendar days of the conclusion of this Action, including all appeals, each party or individual subject to the terms hereof must either return to the producing party or destroy all documents and copies of documents containing the producing party's Confidential or Highly Confidential information, and must destroy all notes, memoranda, or other materials derived from or in any way revealing such information. The party returning and/or destroying the producing party's Confidential and Highly Confidential information must promptly certify in writing its compliance with the requirements of this Paragraph. Notwithstanding the foregoing, outside counsel for a receiving party may retain Confidential and Highly Confidential information to the extent such information is contained in counsel's work product, correspondence between outside counsel, or in copies of pleadings and materials exchanged during discovery or submitted to the Court, subject to the confidentiality provisions of this Protective Order.

19. The United States District Court for the District of Delaware is responsible for the interpretation and enforcement of this Protective Order. All disputes concerning Confidential or Highly Confidential material produced under the protection of this Protective Order shall be

resolved by the United States District Court for the District of Delaware. Every individual who receives any Confidential or Highly Confidential material agrees to subject himself or herself to the jurisdiction of this Court for the purpose of any proceedings related to performance under, compliance with, or violation of this Protective Order.

20. This Protective Order has been agreed to by the parties to facilitate discovery and production of Confidential and Highly Confidential information in this Action. Neither the identification of documents, agreement of the parties, nor the designation of any information, document, or the like as Confidential or Highly Confidential information, nor the failure to make such designation, shall be deemed as an admission of relevance or constitute evidence with respect to any issue in this Action.

21. This Protective Order shall survive the termination of this Action and shall remain in full force and effect unless modified by an Order of this Court or by the written stipulation of the parties filed with the Court.

Respectfully submitted,

May 12, 2016

By: /s/ Francis DiGiovanni

Francis DiGiovanni (#3189)
Curt Lambert (#4882)
DRINKER BIDDLE & REATH LLP
222 Delaware Avenue, Suite 1410
Wilmington, DE 19801
(302) 467-4200

Of Counsel:

Edgar H. Haug
Sandra Kuzmich, Ph.D.
Jonathan A. Herstoff
Michael W. Harkness
FROMMER LAWRENCE & HAUG LLP
745 Fifth Avenue
New York, New York 10151
(212) 588-0800

Attorneys for Plaintiffs

*Shire Development LLC, Shire Canada Inc.,
and Shire International Licensing B.V.*

May 12, 2016

By: /s/ Bindu A. Palapura

David E. Moore (#3983)
Bindu A. Palapura (#5370)
Stephanie E. O'Byrne (#4446)
POTTER ANDERSON & CORROON
LLP
Hercules Plaza, 6th Floor
1313 N. Market Street
Wilmington, DE 19801
(302) 984-6000

Of Counsel:

Steven Feldman
Sherry Rollo
HAHN LOESER & PARKS LLP
125 South Wacker Dr., Suite 2900
Chicago, IL 60606
(312) 637-3000

Attorneys for Defendants

Apotex Inc. and Apotex Corp.

IT IS SO ORDERED.

Dated:

Hon. Christopher J. Burke
United States Magistrate Judge

EXHIBIT A

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

**SHIRE DEVELOPMENT LLC,
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**Civil Action No. 15-1045
(LPS)(CJB)**

**AGREEMENT TO BE BOUND BY
STIPULATED PROTECTIVE ORDER**

I, _____, being duly sworn, state that:

1. My address is _____.
2. My present employer is _____ and the address of my present employment is _____.
3. My present occupation or job description is _____.
4. I have carefully read and understood the provisions of the Protective Order signed by the Court in this Action, and I will comply with all provisions of the Protective Order.
5. I will hold in confidence and not disclose to anyone not qualified under the Protective Order any Confidential or Highly Confidential material, or any words, summaries, abstracts, or indices of Confidential or Highly Confidential material disclosed to me.

6. I will use Confidential or Highly Confidential material disclosed to me solely for purposes relating to this Action.

7. No later than the final conclusion of this Action, I will return or destroy all Confidential or Highly Confidential material and summaries, abstracts, and indices thereof which come into my possession, and documents or things which I have prepared relating thereto, to counsel for the party for whom I was employed or retained.

8. I declare under penalty of perjury that the foregoing is true and correct.

Dated: _____